code__of__federal__regulations/ibr__locations.html.

(b) International Organization for Standardization (ISO), mailing address: ISO, Attn: ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH–1211 Geneva 20, Switzerland, phone (dialing from the United States): 011–41–22–749–0111, and may be ordered online at *http://www.standardsinfo.net*.

(1) ISO/IEC 646:1991(E), Information technology—ISO 7-bit coded character set for information interchange (third edition; December 15, 1991), into §§ 830.20(c) and 830.100(b);

(2) ISO/IEC 15459–2:2006(E), Information technology—Unique identifiers—Part 2: Registration procedures (second edition; March 1, 2006), into §§ 830.20(b) and 830.100(b);

(3) ISO/IEC 15459–4:2008(E), Information technology—Unique identifiers—Part 4: Individual items (second edition; July 15, 2008), into §§ 830.20(b) and 830.100(b);

(4) ISO/IEC 15459–6:2007(E), Information technology—Unique identifiers—Part 6: Unique identifier for product groupings (first edition; June 15, 2007), into §§ 830.20(b) and 830.100(b).

§ 830.20 Requirements for a unique device identifier.

A unique device identifier (UDI) must:

(a) Be issued under a system operated by FDA or an FDA-accredited issuing agency;

(b) Conform to each of the following international standards:

(1) ISO/IEC 15459–2, which is incorporated by reference at § 830.10;

(2) ISO/IEC 15459–4, which is incorporated by reference at § 830.10; and

(3) ISO/IEC 15459–6, which is incorporated by reference at § 830.10.

(c) Use only characters and numbers from the invariant character set of ISO/IEC 646, which is incorporated by reference at § 830.10.

[78 FR 58825, Sept. 24, 2013]

§ 830.40 Use and discontinuation of a device identifier.

(a) Only one device identifier from any particular system for the issuance of unique device identifiers (UDIs) may be used to identify a particular version or model of a device. A particular version or model may be identified by UDIs from two or more systems for the issuance of UDIs.

(b) A device identifier shall be used to identify only one version or model.

(c) In the event that a version or model of a device is discontinued, its device identifier may not be reassigned to another device. If a discontinued version or model is re-introduced and no changes have been made that would require the use of a new device identifier, the device identifier that was previously in use may be used to identify the device.

(d) In the event that an issuing agency relinquishes or does not renew its accreditation, you may continue to use a previously issued UDI until such time as § 830.50 requires you to assign a new device identifier.

[78 FR 58825, Sept. 24, 2013]

§ 830.50 Changes that require use of a new device identifier.

(a) Whenever you make a change to a device that is required to bear a unique device identifier (UDI) on its label, and the change results in a new version or model, you must assign a new device identifier to the new version or model.

(b) Whenever you create a new device package, you must assign a new device identifier to the new device package.

[78 FR 58825, Sept. 24, 2013]

§ 830.60 Relabeling of a device that is required to bear a unique device identifier.

If you relabel a device that is required to bear a unique device identifier (UDI), you must:

(a) Assign a new device identifier to the device, and

(b) Keep a record showing the relationship of the prior device identifier to your new device identifier.

[78 FR 58825, Sept. 24, 2013]

Subpart C—FDA Accreditation of an Issuing Agency

§ 830.100 FDA accreditation of an issuing agency.

(a) *Eligibility*. A private organization may apply for accreditation as an issuing agency.